2. 510(k) Summary

510(k) Summary

Applicant & Submitter:	Care Electronics, Inc.
Address:	4700 Sterling Dr., Suite D Boulder, CO 80301
Phone:	303-444-2273
Fax:	303-447-3502
Contact Person:	Thomas Moody
Preparation Date:	6/21/05
Lamp Submitted:	Dermillume Red Lamp
Proprietary Name:	Dermillume Red
Common Name:	Infrared Therapy Lamp
Classification:	Lamp, Infrared; Class II Product code: ILY
Predicate Lamps:	Biolight PCD (K011355), Biobeam (K042813), Anodyne Therapy Systems (K931261), PremIR 818 (K042532), Dermillume Pro1000 (K043575)
Lamp Description:	The Dermillume Red HR1000 lamp is a compact light source that delivers high intensity narrow band red and near infrared light to the skin surface. The light sources are narrow bandwidth LEDs mounted in an array to give even and safe illumination of skin surfaces. The principal parts of the lamp are a light unit, positioning arm and firmware timer to control duration of exposure.
Intended Use:	The Dermillume Red HR1000 infrared lamp is intended for the relaxation of muscles and relief of muscle spasms, temporary relief of minor muscle and joint aches, pains and stiffness, temporary relief of minor pain and stiffness associated with arthritis, and to temporarily increase local blood circulation.

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510(k) Summary, contd.

Performance Data:

The performance data obtained from bench testing of the Dermillume lamp substantiates that the irradiance at a practicable distance from the skin surface is comparable with the cited predicated lamps.

The mode of operation, technology and general principles of this lamp are the same as the predicate lamps.

There are no significant adverse reactions observed in clinical studies using this technology. The lamp is safe and efficacious.

Substantial Equivalence:

The Dermillume Red HR1000 infrared lamp is substantially equivalent to the cited predicate lamps for spectral output, mode of operation, operating principals as well as general and specific indications for use. Although there are some differences in the source of the emitted light and output intensity, these differences are minor and do not raise new questions of safety or efficacy.

The Dermillume Red HR1000 infrared lamp is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2005

Mr. Thomas O. Moody
President
Care Electronics, Inc.
4700 Sterling Drive, Suite D
Boulder, Colorado 80301

Re: K051681
Trade/Device Name: Dermillume Red, model HR 1000
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: July 8, 2005
Received: July 12, 2005

Dear Mr. Moody:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson, MS
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051681

Lamp Name: Dermillume Red, model HR1000

Indications for Use: The Dermillume Red HR1000 infrared lamp is intended for the relaxation of muscles and relief of muscle spasms, temporary relief of minor muscle and joint aches, pains and stiffness, temporary relief of minor pain and stiffness associated with arthritis, and to temporarily increase local blood circulation.

Prescription Use Yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use Yes (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Lamp Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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